

Claims 1-12, 18-34, and 36-50 are under consideration by the Examiner, claims 13-17 and 35 having been removed from consideration subject to a restriction requirement. Applicants respectfully request reconsideration of the claims in view of the following remarks.

Art-Related Remarks

The Examiner indicated during the interview that the rejections based on Kline *et al.*, U.S. Patent No. 5,459,078, would be withdrawn. See Paper No. 12. The Examiner also indicated in Paper No. 11, part 4, that the rejections based on McGill *et al.*, U.S. Patent No. 5,880,552 (misidentified as U.S. Patent No. 5,459,078) were overcome. Applicants thank the Examiner for reconsidering and withdrawing these rejections.

The only rejections remaining are those under 35 U.S.C. §102 and 35 U.S.C §103, based on Brecht *et al.* (Anal. Chim. Acta, 1995, vol. 311, pp 289-299), alone and in combination with Goddard *et al.* (Analyst, 1994, vol. 119, pp. 583-588); Goddard *et al.* in further view of Buechler *et al.* (U.S. Patent No. 5,458,852) and Finlan (U.S. Patent No. 5,055,265); and in view of Goddard *et al.* in further view Kimock *et al.* (U.S. Patent No. 5,637,353. Applicant respectfully traverses these rejections.

Anticipation by Brecht *et al.* of claims 1, 2, 18-20, 23, 24, and 36

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. Furthermore, the claims must be interpreted in light of the teachings of the specification. *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). See also MPEP § 2131.

As discussed in Applicants' previous response, the optical assay devices of instant claims 1, 2, 18-20, 23, 24, and 36 comprise a support and an optically functional layer positioned on the support, and are configured such that laminar flow of a sample is permitted through the layers of the device. See, e.g., claim 1. In several claims, the support is further described as containing channels (e.g., claim 1) or as being porous (e.g., claim 3). Such channeled and porous supports can provide for laminar flow through the device layers. See, e.g., specification, page 5, line 23, through page 6, line 16.

In contrast, the Brecht *et al.* reference discloses a glass surface mounted on a flow cell. Brecht *et al.*, page 292, "Setup." Unlike the instantly claimed devices, reagent flow in the devices of the Brecht *et al.* reference does not occur through the layers of the device, but rather across the device surface. *Id.* ("Glass chips were mounted on a flow cell with the interference layers facing the cell volume, [with] inlet and outlet at opposite sides of the cell lumen"). Therefore, because the Brecht *et al.* reference does not disclose devices comprising a support that allows laminar flow of a sample through the layers of the device, the instant claims are not anticipated by Brecht *et al.*

In Paper No. 11, the Examiner does not address this element of the instantly claimed devices, instead referring only to Applicants' remarks concerning laminar flow. In the previous Office Action, however, the Examiner stated that the Brecht *et al.* reference discloses a "channel for sample flow." Paper No. 7, page 4. Applicants disagree that the Brecht *et al.* reference shows any "channels," and reiterate that the Brecht *et al.* reference does not show a support that provides laminar flow through the layers of the device, as required by the instant claims.

Therefore, because the Brecht *et al.* reference does not disclose devices that provide laminar flow of a sample through the layers of the device, claims 1, 2, 18-20, 23, 24, and 36 are not anticipated by Brecht *et al.* Accordingly, Applicants respectfully request that the rejection under 35 U.S.C §102(b) be withdrawn.

Moreover, with regard to Applicants' remarks concerning laminar flow, the Examiner states that "Brecht *et al.* recognizes that their cell is not a true laminar flow cell." Paper No. 11, part 2. Nevertheless, the Examiner contends that the Brecht *et al.* reference anticipates the instantly claimed invention because the Brecht *et al.* reference states "that the laminar flow cell had superior performance," and thus the artisan would recognize that "more laminar-like flow characteristics would be an improvement." *Id.* Applicants respectfully submit that the Examiner is confusing an obviousness rejection for anticipation. The instant claims comprise supports that promote laminar flow through the layers of the device. If the Examiner concludes that no such flow is provided by the Brecht *et al.* reference, then an anticipation rejection cannot be supported. In an effort to advance prosecution, however, Applicants address the Examiner's contentions below.

The Brecht *et al.* reference does not state that the “laminar flow” cell had superior performance to the “wall jet” cell, as the Examiner contends. As discussed on page 292, right column, the Brecht *et al.* reference tests, not only two flow cells, but also two different detectors, a Zeiss MCS and a Zeiss MMS. On page 295, the Brecht *et al.* reference states “[i]nhibition experiments were carried out with the MCS spectrometer and the laminar flow cell, as results indicated that this setup gives the best performance” (emphasis added). The ordinarily skilled artisan will understand that improvement in performance is more likely due to selection of the MCS detector, rather than selection of the flow cell. For example, on pages 295 and 296, the Brecht *et al.* reference states that the MCS detector has superior noise characteristics (“baseline noise values of 7.0 pm rms (MCS) and 13.4 pm rms (MMS)”) and the ability to average more data per data point (“with the MCS spectrometer 25 spectra per data point could be averaged, while with the MMS spectrophotometer this value was limited to one spectrum”). Thus, the Brecht *et al.* reference clearly shows the superiority of the MCS detector over the MMS detector. See, e.g., Brecht *et al.*, page 295, right column (“In the current study the limiting factors are the spectrometer resolution, the diode spacing and the number of spectra summed for each data point.”).

In contrast, the Brecht *et al.* reference equally clearly states that the “laminar flow” cell provides no gain in performance versus the “wall jet” cell. For example, in figures 7 and 8, the Brecht *et al.* reference shows that an increase in assay response, measured by an increase in slope of the calibration curve, is obtained in the “wall jet” cell, and not in the “laminar flow” cell. Moreover, as stated on page 296, right column, any increase in signal is accompanied by an increase in the standard deviation of the measurements, so that “no analytical performance was gained” in changing flow cells. The ordinarily skilled artisan would understand that a device that increases signal without any gain in analytical performance is of no use whatsoever. Furthermore, while the Examiner states that the Brecht *et al.* reference discloses that “signal can be increased by improvement of mass transport to the sensor surface” (Paper No. 11, part 7, emphasis added), this does not suggest that a device that comprises laminar flow through the layers of the device, as instantly claimed, either could be produced, or that, if produced, would provide any benefit whatsoever. Thus, in the absence of the teachings of the instant invention,

the Brecht *et al.* reference would not motivate the ordinarily skilled artisan to produce the instantly claimed devices.

Accordingly, the instantly claimed devices, which provide laminar flow through the layers of an optical assay device, are neither disclosed nor suggested by the Brecht *et al.* reference.

Obviousness rejections based on Brecht *et al.*

To establish a *prima facie* case of obviousness, three criteria must be met: there must be some motivation or suggestion, either in the cited references or in knowledge available to one skilled in the art, to modify or combine the cited references; there must be a reasonable expectation of success in combining the references to achieve the claimed invention; and the references must teach or suggest all of the claim limitations. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP § 2143.

As discussed above, the Brecht *et al.* reference does not disclose, or even suggest, optical assay devices comprising a support that provides laminar flow of a sample through the layers of the support. The secondary references cited by the Examiner do not cure the deficiencies of the Brecht *et al.* reference; nor does the Examiner contend that they do so. For example, Goddard *et al.* is offered for its alleged disclosure of an antireflective coating (Paper No. 7, page 8); Beuchler *et al.* and Finlan are offered for its alleged disclosure of materials for use in a support (Paper No. 7, page 10); and Kimock *et al.* is offered for its alleged disclosure of DLC coatings (Paper No. 11, part 9). Thus, even if the references are combined, as suggested by the Examiner, the resulting combination does not disclose or suggest the claimed optical assay devices comprising a support that provides laminar flow of a sample through the layers of the support.

New rejection based on Brecht *et al.* in view of Kimock *et al.*

Furthermore, with regard to the rejection of claims 38 to 50 based on Brecht *et al.* in combination with the Kimock *et al.* reference, the Examiner contends that “the claims are drawn to a device wherein a diamond like carbon surface is used to support an attachment layer.” Paper No. 11, part 9. This is incorrect. The claims are actually drawn to a device having an attachment

layer that comprises diamond like carbon ("DLC"). As discussed in the specification on page 34, line 10, through page 35, line 25, the attachment layer is used to promote adhesion of the analyte-specific capture layer, or to non-specifically capture an analyte, and does not significantly contribute to the optical characteristics of the device. Thus, the attachment layer must be placed on the device surface in a position to interact with either the capture layer or with the analyte itself. The instant specification describes that DLC can comprise such an attachment layer. *See, e.g.*, specification, page 40, lines 6-20.

In contrast, the Kimock *et al.* reference is related to wear-resistant coatings. The Examiner contends that Kimock *et al.* reference discloses the properties of DLC coatings related to transparency and high refractive index. But, the Kimock *et al.* reference is completely unrelated to materials to be used for bioattachment. Thus, the reference is not "reasonably pertinent to the particular problem with which the inventor was concerned," and therefore is not available as a reference under 35 U.S.C. § 103. *See* MPEP § 2141.01(a). Moreover, nothing of record discloses or suggests that DLC be used as an attachment layer. Without such knowledge, even if the skilled artisan were to use a DLC layer for its optical properties, there would be no motivation to place the DLC layer on the device surface in a position to interact with a capture layer or an analyte. Therefore, merely using a DLC layer in an optical device would not inherently provide an attachment layer.

Therefore, because the cited references fail to teach or suggest all of the claim limitations, the Examiner has failed to establish a *prima facie* case of obviousness. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C §103(a) be reconsidered and withdrawn.

### CONCLUSION


Applicants respectfully submit that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the

Examiner is encouraged to contact the undersigned at the address and telephone number listed below so that they may be resolved without the need for additional action and response thereto.

Respectfully submitted,

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Dated: 12/15/00

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